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| 09 853,343 | 05 10 2001 | Allan Bradley | 11635-005001 OTA 00-43 | 8644 |

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 05 30 2003

111

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/853,343

Applicant(s)

BRADLEY ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-103 is/are pending in the application.
- 4a) Of the above claim(s) 58-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-57 and 82-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PDA) (4)
- 3) ☐ Information Disclosure Statement (IDS) (PTO-1449, Paper No. 14)
- 4) ☐ Interview Summary (PTO-413) (Paper No. 14)
- 5) ☐ Notice of Informal Patent Application (NIPA) (PTO-101)

DETAILED ACTION

1. Applicants' response to the office action (Paper No. 13) filed on March 4, 2003 has been entered and considered.
2. Claims 1-57, 82-83 are considered for examination in the previous office action. Claims 58-81 are non-elected and hence are withdrawn from further consideration. Claims 84-103 are newly added and are considered for examination.

Response to arguments

3. Applicants' response to the office action (Paper No. 13) is fully considered and found persuasive in part.
4. With reference to the rejection under 35 USC 112, second paragraph, Applicants amendment and arguments are fully considered and the rejection is withdrawn herein in view of the amendment (Paper No. 13).
- 5A. The following is the rejection made in the previous office action under non statutory double patenting:

Claims 1-3, 13, 18-24, and 84-103 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 18-20 of U.S. Patent No.6,048,695 ('695). Although the conflicting claims are not identical, they are not patentably distinct from each other because the biological molecule of the instant claims encompasses nucleic acids as claimed in the patented claims ('695). Biological molecule comprises a nucleic acid (DNA or RNA), a protein, or a peptide, lipid or a polysaccharide. The instant claims are directed to a biological molecule in the instant claims. The instant claims differ from patented claims only in reciting "biological

molecule' in place of 'nucleic acid' which is an obvious variation of the term nucleic acid. Further the high-density microarray disclosed in the patented claims is recited as article in the instant claims. Therefore, the instant claims are not patentably distinct and hence are rejected under obviousness-type double patenting.

Response to Arguments:

Applicants' arguments are considered and the rejection is maintained since Applicants' did not submit a terminal disclaimer.

The newly added claims 84-103 are also rejected under nonstatutory double patenting over the said patent (USPN.6,048,695) herein because the patented claims 1-23, 25-28, 33-34, 51 encompass the instant claims as discussed above. Therefore the instant new claims are rejected as being obvious over the claims in the said patent.

5B. The following is the rejection made in the previous office action under statutory double patenting:

Claims 1-3, 8-11, 18-28, and 54 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 8-25, and 27-32 of prior U.S. Patent No. 09/ 546,085. This is a double patenting rejection.

Response to Arguments:

Applicants arguments are fully considered and found persuasive. However, the instant claims along with the newly added claims of the instant application are rejected under nonstatutory double patenting as discussed below

a. Claims 1-3, 8-11, 18-20, 22, and 84-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Krinski et al. (USPN. 4,713, 116).

Krinski et al. teach a modified biological molecule (protein) wherein Krinski et al. teach that the modified biological molecule comprises a biological molecule covalently bound to a compound having formula R_1-X-R_2 and the compound could be glycidoxypolytrimethoxysilane (see column 3, lines 8-10, column 4, lines 31-41). Krinski et al. also teaches that the modified biological molecule could be a protein material, a peptide or a polypeptide (see column 4, lines 31-53); the alkoxysilane could be a polytrimethoxy silane (see column 4, lines 31-41); and could include addition of amino groups to the modified biological molecule (see column 4, lines 54-67). Thus, the disclosure of Krinski et al. meets the limitations in the instant claims.

Response to arguments:

Applicants' arguments are fully considered and found persuasive in part. Applicants agree that Krinski et al. teach only modifying protein materials with organosilanes such as the alkoxysilane 3-glycidoxypolytrimethoxysilane. Thus the instant claims 1-3, 18-19 are anticipated by Krinski et al. The instant claim recites "a composition comprising, an antibody or a small molecule" which meets the limitations in the prior art, because an antibody is a protein and a small molecule could comprise any polypeptide, or protein material. Applicants' argument regarding no suggestion or teaching of adding an amino group is fully considered and found persuasive. Hence the instant claims 8-11, 20, 22 are not anticipated by Krinski et al. and

the examiner is of the opinion that the instant claims are not

The new claim 84- 87 are also rejected under 35 USC 102(b) as anticipated by Krinski et al. because the claim limitations meet the teachings as disclosed by Krinski et al. as discussed in the above rejection.

6B. The following rejections were made in the previous office action under 35 USC 102(b):

(b) Claims 1-3,12-13, 15, 23-28, are 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Plueddemann (USPN. 4,231,910).

Plueddemann teaches a modified biological molecules (primer compositions) on a solid support wherein Plueddemann discloses a solid support and immobilized modified biological molecules (see column 2, lines 21-39, column 3, lines 22-29). Plueddemann also teaches that (i) the solid support comprises glass, quartz, aluminum, titanium, and metal oxides (see column 3, lines 22-29); and (ii) solid support could also comprise polyesters, polycarbonates, polyethylene terephthalate, and nylon (column 3, lines 30-54). Thus the disclosure of Plueddemann meets the limitations in the instant claims.

Response to arguments:

Applicants' arguments and amendment are fully considered and the rejection is withdrawn in view of the amendment (Paper No. 13).

6C. The following rejections were made in the previous office action under 35 USC 102(e):

(c) Claims 1-3,12-15, 23-28, 32-38, 47, and 82-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Beattie (USPN. 6,426,183).

(oligonucleotides) immobilized to said solid support (see column 3, lines 1-4). Beattie also

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disclose that (i) the solid support comprises silane containing substrates which include hydroxyl groups (see column 4, lines 46-54, column 3, lines 5-9); (ii) solid support comprises glass, quartz, metal oxides (see column 4, lines 13-36); and (iii) biological molecules on solid support are immobilized in discrete spots at a suitable distance from one another, typically from about 0.01 to 10mm of one another (see column 12, lines 25-31); (iv) nucleic acid comprises plurality of CpG island tags (see column 8, lines 10-28); and (v) method of making modified biological molecule and method of making a microarray comprising modified biological molecule (see 2, lines 12-67, and column 3, lines 1-15). Thus the disclosure of Beattie meets the limitations in the instant claims.

Response to arguments:

Applicants' arguments and amendment are fully considered and found not persuasive. Applicants' particular argument that Beattie did not teach a biological compound having at least an amino group and hydroxy group attached to a silane containing substrate, is found not persuasive because Beattie does teach attaching a modified compound comprising at least an amine and hydroxy group (e.g. aminopropanol containing compound) to a silaceous or silane-containing substrate (see abstract of the patent 6, 426, 183, column 2, lines 35-52). Thus the disclosure of Beattie meets the limitations in the instant claims and the rejection is maintained herein.

Further instant claims 84-91 are rejected herein under 35 USC 102(e) as anticipated by

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DNA, peptides, or a protein (see column 7, lines 34-67, column 8, lines 10-28). Thus the disclosure of Beattie also meets the limitations in the instant claims.

7. With reference to the rejection made in the previous office action made under 35 USC 103(a), Applicants' arguments and amendments are fully considered and the rejection is withdrawn in view of the amendment (Paper No.13).

New Grounds of rejections

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-57, and 82-103 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-41, 63-64, 78-88 of copending Application No. 09/ 546,085. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a composition comprising a nucleic acid, a polysaccharide or a saccharide, a lipid, an antibody or a small cyclic group or an amino group, R, is an alkoxysilane group, and X is a moiety linking the cyclic ether group or amino group and the alkoxysilane group. The claims in the co-ending applications

encompass the instant claims. The instant claims differ from the claims in the co-pending application only in reciting "R₁ as a cyclic ether group or an amino group", which is an obvious variation. Further the high-density microarray disclosed in the claims of the co-pending application encompass the instant claims. Therefore, the instant claims are not patentably distinct over the claims in the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

a. Claims 1-3, 11-15, 18, 20, 22, 84-91, 95, 100-102 are rejected under 35 U.S.C. 102(e) as being anticipated by Gray et al. (USPN. 5,851, 769).

Gray et al. teach a modified biological molecule (nucleic acid) and a solid support wherein Gray et al. teach that the modified biological molecule comprises a biological molecule covalently bound to a compound having formula R₁-X-R₂, wherein R₁ is an amino group, R₂ is an alkoxy silane group, X is a linking moiety, and the compound includes 3-aminopropyl-

the solid support to which the said biological molecule is attached comprises a glass, or mica or a

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metal oxide surface (see column 19, lines 49-67, column 20, lines 1-6). Thus the disclosure of Gary et al. meets the limitations in the instant claims.

Conclusion

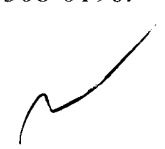
No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha ^{SPC}Chunduru
May 28, 2003


JEFFREY FRIEDMAN
PRIMARY EXAMINER